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SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Indication Expansion – FOOTPRINT Ultra PK suture anchors

Date Prepared: November 4, 2011

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover MA, 01810

B. Company Contact

Melissa Egan, M.Sc.

Regulatory Affairs Specialist II

Phone: (508) 261-3645

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B. Device Name

Trade Name:	FOOTPRINT Ultra PK suture anchor
Common Name:	Suture Anchor
Classification Name:	Fastener, fixation, nondegradable, soft tissue

D. Predicate Devices

The indication of distal row abductor tendon repair is substantially equivalent to the currently marketed indications for use of the following legally marketed device in commercial distribution: The Smith & Nephew FOOTPRINT Ultra PK suture anchor (K093897) and the Arthrex Corkscrew suture anchor (K061665).

E. Description of Device

The FOOTPRINT Ultra PK is a suture anchor manufactured from polyetheretherketone. The tap-in anchor incorporates an anchor and plug and is

pre-assembled on an inserter. The anchor accommodates up to four strands of suture and is offered diameters of 4.5 mm and 5.5 mm.

F. Intended Use

The intended use of the currently available suture anchors remains unchanged. The suture anchors are intended for fixation of soft tissues to bone for the following indications:

Shoulder: Rotator cuff repair, Bankart repair, Slap lesion repair, Biceps tenodesis, Acromio-Clavicular separation, Deltoid repair, and Capsular shift or Capsulolabral reconstruction.
Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, Hallux valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair.
Knee: Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Iliotibial band tenodesis.
Hand/Wrist: Scapholunate ligament reconstruction, Ulnar collateral ligament reconstruction, Radial collateral ligament reconstruction.
Elbow: Biceps Tendon reattachment, Ulnar or radial collateral ligament reconstruction.
Hip: Distal row abductor tendon repair

G. Comparison of Technological Characteristics

Since there are no changes to the design the technological characteristics remain the same.

H. Summary Performance Data

Clinical literature has shown equivalence between repair techniques for shoulder rotator cuff and hip abductor tendon repair. The performance testing conducted includes static and dynamic loading properties that are substantially equivalent to the indicated predicates. Testing also demonstrates that the differences in the FOOTPRINT Ultra PK suture anchor and the predicate does not raise any issues of safety and efficacy for distal row abductor tendon repair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Incorporated, Endoscopy Division
% Melissa Egan, M.Sc.
Regulatory Affairs Specialist II
150 Minuteman Road
Andover, Massachusetts 01810

MAR - 6 2012

Re: K113274
Trade/Device Name: FOOTPRINT Ultra PK suture anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 29, 2012
Received: March 1, 2012

Dear Ms. Egan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113274

Device Name: FOOTPRINT Ultra PK suture anchor

Indications for Use:
The Smith & Nephew FOOTPRINT Ultra PK suture anchor family is intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Rotator cuff repair, Bankart repair, Slap lesion repair, Biceps tenodesis, Acromio-Clavicular separation, Deltoid repair, and Capsular shift or Capsulolabral reconstruction.

Foot/Ankle: Lateral stabilization, Medial stabilization, Achilles tendon repair, Hallux valgus reconstruction, Mid-foot reconstruction, Metatarsal ligament repair.

Knee: Medial collateral ligament repair, Lateral collateral ligament repair, Patellar tendon repair, Posterior oblique ligament repair, Iliotibial band tenodesis.

Hand/Wrist: Scapholunate ligament reconstruction, Ulnar collateral ligament reconstruction, Radial collateral ligament reconstruction.

Elbow: Biceps Tendon reattachment, Ulnar or radial collateral ligament reconstruction.

Hip: Distal row abductor tendon repair.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113274